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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,502	12/28/2000	Lisa A. Tam	13364	9486

7590 07/07/2005

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EXAMINER

COLE, MONIQUE T

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/752,502

Applicant(s)

TAM ET AL.

Examiner

Monique T. Cole

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2 is/are allowed.
- 6) ☒ Claim(s) 1 and 3-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 6, 7, 8, 9, 10, 11, 12, 14, 19, 20, 21, 23 & 24 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,638,769 to Lilja et al. (herein referred to as "Lilja").

Lilja teaches a method and device for hemoglobin determination that provides a housing; a microcuvette holder for receiving the sample; a photometer that contains suitable filters and light emitting diodes with a built in microprocessor. Absorption is measured at 49-520 nm and may also be measured in the wavelength of 850-910 nm. With regard to claims 3, 9, 11, 14, 19, 20, 23 & 24, these claims do not serve to structurally limit the claimed device, so for examination purpose they do not provide a patentable distinction over the prior art and are being included in this rejection.

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3. Claims 1, 3, 4, 6, 7, 8, 9, 10, 11, 12, 11, 14, 15, 16, 17, 19, 20, 21, 23 & 24 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,379,969 to Mauze et al. (herein referred to as "Mauze").

Mauze teaches a hand-held skin-pricking device (col. 4, lines 16-17) for analyzing fluids. The device comprises a light source 14; processor 16; light detector 18; light receiving sensor array apparatus 20, 22; and holder 50. The light sources can emit light ranging from 500-700 to be detected by pH sensitive dyes (Table 3). The light sources may be lasers, diodes or incandescent sources (col. 6, lines 6-10). The sensor array may have 10 sensors which each have a different light source (col. 5, lines 18-30, 51-58). With regard to claims 3, 9, 11, 14, 19, 20, 23 & 24, these claims do not serve to structurally limit the claimed device, so for examination purpose they do not provide a patentable distinction over the prior art and are being included in this rejection.

4. Claims 1, 3, 4, 5, 7, 8, 9, 13, 14, 15, 19, 20, 21, 23 & 24 are rejected under 35 U.S.C. 102(b) as being anticipated by USP 5,567,869 to Hauch et al. (herein referred to as "Hauch").

Hauch teaches a handheld skin-pricking device that comprises a housing; a cuvette holder for the sample; a light source; means for measuring the light; means for recording the light; means for calculating; and display means. See col. 2, line 62-col. 3, line 2. Hauch teaches that if reflectance is measured the sensor is placed so that it would receive no light directly from the light source. One or more light sources 7 & 9 may be used (col 3, line 65-col. 4, line 6). With regard to claims 3, 9, 11, 14, 19, 20, 23 & 24, these claims do not serve to structurally limit the

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claimed device, so for examination purpose they do not provide a patentable distinction over the prior art and are being included in this rejection.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mauze in view of Hauch.

The handheld skin-pricking device of Mauze does not expressly teach the orientation of the light receiving detectors to the component used to measure the reflectance of the sample.

Hauch teaches a handheld skin-pricking device that teaches that if reflectance is measured the sensor is placed so that it would receive no light directly from the light source. Given the teaching of Hauch, it would have been obvious to one having ordinary skill in the art to modify Mauze by arranging the light receiving detectors to the component used to measure the reflectance of the sample to lie in the same plane so that the device would be better able to measure the sample reflectance.

7. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hauch in view of USP 4,003,662 to Retzer et al. (herein referred to as "Retzer").

Hauch does not expressly teach that the handheld device is battery powered.

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Retzer teaches a similar device that is battery powered. This lends to increased portability of the device. It would have been obvious to one of ordinary skill to modify the Hauch reference by making the device battery powered to improve the portability of the device and make it more accessible for at-home & emergency use.

8. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mauze in view of Retzer

Mauze does not expressly teach that the handheld device is battery powered.

Retzer teaches a similar device that is battery powered. This lends to increased portability of the device. It would have been obvious to one of ordinary skill to modify the Mauze reference by making the device battery powered to improve the portability of the device and make it more accessible for at-home & emergency use.

Response to Arguments

1. Applicant's arguments filed 4/12/2005 have been fully considered but they are not persuasive.

Lilja reference

Applicant's arguments that Lilja does not teach that the number of light sources or filters in the visible region of the electromagnetic spectrum be less than or equal to the number of hemoglobin derivatives to be measured is wrong. Lilja teaches at least one light source and at least one hemoglobin derivative, thus meeting the disputed claim limitation.

Additionally, Lilja does teach the microprocessor see col. 4, lines 35-36 where it is expressly taught that the built in microprocessor calculates.

Mauze reference

Applicant argues that Mauze does not teach a housing, however of course the housing is present to encompass all of the aspects of the apparatus col. 3, lines 25-45. With regard to the lack supposed lack of the holder, the device is capable of transporting fluid from the skin, thus there is a holder for the blood.

Hauch reference

The reference explicitly provides a means for calculating, thereby meeting the microprocessor limitation. With regard to the number of light sources, there is at least one light source to the at least one hemoglobin sample.

103 Rejections

It is not clear how applicant's comments are relevant, so the Examiner is unsure of how to respond.

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Allowable Subject Matter

2. Claim 2 is allowed.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

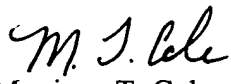
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 571-272-1255. The examiner can normally be reached on Monday, Tuesday & Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Monique T. Cole
Primary Examiner
Art Unit 1743

mtc